#### **PATENT**

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Sokawa & Liu

APPLICATION No.: Unassigned

FILED: Concurrently Herewith

FOR: METHOD OF TREATMENT USING

INTERFERON-TAU

EXAMINER: Unassigned

ART UNIT: Unassigned

# Information Disclosure Statement Accompanying Petition to Make Special

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

#### 1. <u>Timing of Submission</u>

This information disclosure is being filed concurrent with a Petition to Make Special. It is also being filed within three months of the filing date of this application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever occurs last [37 C.F.R. § 1.97(b)].

The references listed on the enclosed Form PTO-1449 (modified) may be material to the examination of this application; the Examiner is requested to make them of record in the application. The references most pertinent to the presently pending claims are discussed and distinguished in the accompanying Statement Regarding Preexamination Search and the Preliminary Amendment.

#### 2. <u>Cited Information</u>

- - The following cite nos.: 10, 12, 14, 17-19, 21, 23-24, 27, 34-37, 46, 51, 55, 59, 62-64, 66, 69-72, 77, 79, and 85.
- Copies of the following references can be found in parent U.S. Application No. 09/910,406:
  - The following cite nos.: 20, 22, 30-31, 38-42, 44-45, 47-50, 52-53, 58, 60-61, 65, 67-68, and 81-84.

Copies of the following references can be found in parent U.S. Application No. 10/346,269:

- The following cite nos.: 25-26, 28-29, 32-33, 43, 54, 56-57, 73-76, 78, and 80.
- This application was filed after 30 June 2003, therefore no copies of U.S. patents or published applications are required (See Notice of Deputy Commissioner Kunin on 11 July 2003). However, copies of U.S. patents discussed in the accompanying Statement Regarding Preexamination Search and the Preliminary Amendment are enclosed for the Examiner's convenience.

### 3. <u>Fee Payment</u>

No fees are believed due because this Information Disclosure Statement is being filed before the mailing date of the first Office Action.

However, should the Commissioner determine that fees are due in order for this Information Disclosure Statement to be considered, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2207.

Respectfully submitted,

Date: 21 November 2003

Judy M. Mohr

Registration No. 38, 563

### **Correspondence Address:**

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Perkins Coie LLP
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Form PTO-1449 (Modified) (Use several sheets if necessary)

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| Examiner Name        | Unassigned            |  |
| Attorney Docket No.  | 55600-8013.US01       |  |

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|                      | 1  | _             | 4,683,195           |                                  |          | Mullis, et al.                                     | 07/28/87   |  |   |
|                      | 2  | ,             | 4,683,202           |                                  |          | Mullis   | 07/28/87   |  |   |
|                      | 3  |               | 4,766,068           |                                  |          | Oeda, et al.                                       | 08/23/88   |  |   |
|                      | 4  |               | 4,769,238           |                                  |          | Rutter   | 09/06/88   |  |   |
|                      | 5  |               | 5,019,382           |                                  |          | Cummins, Jr.                                       | 05/28/91   |  |   |
|                      | 6  | ,             | 5,372,808           |                                  |          | Blatt & Taylor                                     | 12/13/94   |  |   |
|                      | 7  |               | 5,438,040           |                                  |          | Ekwuribe   | 08/01/95   |  |   |
|                      | 8  |               | 5,738,845           |                                  |          | Imakawa  | 04/14/98   |  |   |
|                      | 9  |               | 5,882,640           |                                  |          | Cummins  | 03/16/99   |  |   |
|                      | 10   | )             | 5,906,816           |                                  |          | Soos, et al.                                       | 05/25/99   |  |   |
|                      | 11   |               | 5,910,304           |                                  |          | Cummins  | 06/08/99   |  |   |
|                      | 12   | ?             | 5,958,402           |                                  |          | Bazer, et al.                                      | 09/28/99   |  |   |
|                      | 13 6,036,949 Richards & Sherv<br>14 6,060,450 Soos, et al. |               | Richards & Sherwood |                                  | 03/14/00 |  |  |  |   |
|                      |  |               | Soos, et al.        | 05/09/00                         |          |  |  |  |   |
|                      | 15   | 5             | 6,191,105           |                                  |          | Ekwuribe, et al.                                   | 02/20/01   |  |   |
|                      | 16   | 6             | 6,346,243           |                                  |          | Brod   | 02/12/02   |  |   |
|                      | 17   | '             | 6,372,206           |                                  |          | Soos, et al.                                       | 04/16/02   |  |   |
|                      |  |               |                     |                                  |          |  |  |  |   |
|                      |  |               |                     |                                  | FOR      | EIGN PATENT DOCUMENTS                              |  |  |   |
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|                      | 18   | PCT           | WO 90/0             | 1                                |          | Bazer & Johnson                                    | 09/07/90   |  |   |
|                      | 19   | PCT           | WO 94/              | 10313                            |          | Bazer, et al.                                      | 05/11/94   |  |   |
|                      | 20   | PCT           | WO 00/7             | 8266                             |          | Pontzer, et al.                                    | 12/28/00   |  |   |
|                      | 21   | PCT           | WO 96/2             | 8183                             |          | Soos, et al.                                       | 09/19/96   |  |   |

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### OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

EXAMINER

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Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application(s).

Bazer, et al.

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| Examiner Name        | Unassigned            |  |
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|----------------------|-------------|---|---|
|                      | 23          | Adah, S.A., et al., Current Medicinal Chemistry 8:1189-1212, (2001).  |   |
|                      | 24          | Alexenko, A.P., et al., Journal of Interferon and Cytokine Research 17:769-779, (1997).   |   |
|                      | 25          | Amidon, G.L., et al., Peptide and Protein Drug Delivery, Alfred Benzon Symposium 43:146-152, (1998).  |   |
|                      | 26          | Bayley, D., et al., J Pharm Pharmacol <u>47</u> :721-724, (1995).   |   |
|                      | 27          | Bernkop-Schnürch, A. and Gilge, B., <i>Drug Development and Industrial Pharmacy</i> 26(2):107-113, (2000).  |   |
|                      | 28          | Bocci, V., Journal of Biological Regulators and Homeostatic Agents 4(2):81-83, (1990).  |   |
|                      | 29          | Bocci, V., Journal of Interferon and Cytokine Research 19:859-861, (1999).  |   |
|                      | 30          | Bartol, F.F., et al., Biology of Reproduction 33:745-759 abstract only (1985).  |   |
|                      | 31          | Bazer, F.W. and Johnson, H.M., <i>AJRI</i> <u>26</u> :19-22 (1991).   |   |
|                      | 32          | Brod, S.A., et al., Neurology <u>44</u> :1144-1148, (1994).   |   |
|                      | 33          | Brod, S.A., et al., Journal of Interferon and Cytokine Research 15:115-122, (1995).   |   |
|                      | 34          | Brod, S.A., <i>Arch Neurol</i> <u>54</u> :1300-1302, (1997).  |   |
|                      | 35          | Brod, S.A., et al., <i>Diabetologia</i> <u>41</u> :1227-1232, (1998).   |   |
|                      | 36          | Brod, S.A., Journal of Interferon and Cytokine Research 19:841-852, (1999).   |   |
|                      | 37          | Castelli, J., et al., <i>Biomed &amp; Pharmacother</i> <u>52</u> :386-390, (1998).  |   |
|                      | 38          | Choo, QL., et al., Science <u>244</u> :359-362 (1989).  |   |
|                      | 39          | Choo, QL., et al., Proc. Natl. Acad. Sci. USA, <u>88</u> :2451-2455 (1991).   |   |
|                      | 40          | Clayette, P., et al., <i>Pathologie Biologiel</i> , <u>47</u> (4):553-559 (1999).   |   |
|                      | 41          | Cotler, S.J., et al., Journal of Viral Hepatitis 7:211-217 (2000).  |   |

| EXAMINER   |   | DATE CONSIDERED   |
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|            |   |   |
| *EXAMINER: | Initial if reference considered, whether or not criteria is in conformation | nce with MPEP 609. Draw line through citation if not in conformance and not |
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|                                       | 42          | Cross, J.C., et al., Proc. Natl. Acad. Sci. USA <u>88</u> :3817-3821 (1991).  |             |
|                                       | 43          | Dianzani, F., Journal of Interferon Research pps. 109-118, (1992).  |             |
|                                       | 44          | Dieperink, E., et al., Am. J. Psychiatry <u>157</u> :867-876 (2000).  |             |
|                                       | 45          | Ecker, D.J., et al., Journal of Biological Chemistry <u>264</u> (13):7715-7719 (1989).  |             |
|                                       | 46          | Eiamtrakarn, S., et al., <i>Biomaterials</i> <u>23</u> :145-152, (2002).  |             |
|                                       | 47          | Gnatek, G.G., et al., Biology of Reproduction 41:655-663 (1989).  |             |
|                                       | 48          | Helmer, S.D., et al., J. Reprod. Fert., 79:83-91 (1987).  |             |
|                                       | 49          | Imakawa, K., <i>et al.</i> , <i>Nature</i> , <u>330</u> :377-379 (1987).  |             |
|                                       | 50          | Imakawa, K., et al., Molecular Endocrinology, 3:127-139 (1989).   | T           |
| *                                     | 51          | Jacobs, B.L., et al., <i>Virology</i> <u>219</u> :339-349, (1996).  |             |
|                                       | 52          | Jarpe, M.A., <i>et al.</i> , <i>Protein Engineering</i> <u>7</u> (7):863-867 (1994).  |             |
|                                       | 53          | Jiménez-Sáenz, M., et al., Journal of Gstroenterology and Hepatology 15:567-569 (2000).   | T           |
|                                       | 54          | Johnson, H.M.47, et al., Scientific American <u>270</u> (5):40-47, (1994).  |             |
|                                       | 55          | Le Page, C., et al., <i>Rev Immunogenetics</i> <u>2</u> :374-386, (2000).   |             |
| · · · · · · · · · · · · · · · · · · · | 56          | Milstein, S.J., et al., Journal of Controlled Release 53:259-267, (1998).   | T           |
|                                       | 57          | Lawson, C.M. and Beilharz, M.W., <i>Journal of Interferon and Cytokine Research</i> 19:863-867, (1999).   |             |
|                                       | 58          | Magrin, S., et al., Hepatology <u>19</u> :273-279 (1994).   |             |
|                                       | 59          | Nakajima, A. and Sokawa, Y., <i>Journal of Interferon and Cytokine Research</i> 22:397-402, (2002).   | T           |
|                                       | 60          | Ott, T.L., et al., Journal of Interferon Research 11:357-364 (1991).  | T           |

5

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|            |   |   |
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| <del>_</del>         | 61  | Pawlotsky, JM., et al., Journal of Interferon and Cytokine Research <u>15</u> :857-862 (1995).  |       |  |  |
|                      | 62  | Pontzer, C.H., et al., Biochem Biophys Res Communications 152(2):801-807, (1988).   |       |  |  |
|                      | 63  | Pontzer, C.H., et al., <i>Pro Natl Acad Sci USA</i> <u>87</u> :5945-5949, (1990).   |       |  |  |
|                      | 64  | Reddy, S.M., et al., <i>Drugs of Today</i> <u>35(7)</u> :537-580, (1999).   |       |  |  |
|                      | 65  | Roberts, R.M., et al., Endocrine Review <u>13(3):432-452</u> (1992).  |       |  |  |
|                      | 66  | Roberts, R.M., et al., <i>J Interferon Cytokine Res</i> <u>18</u> :805, (1998).   |       |  |  |
|                      | 67  | Saez-Royuela, F., et al., <i>Hepatology</i> <u>10</u> (4):646 (1989).   |       |  |  |
|                      | 68  | Saito, H., et al., Journal of Viral Hepatitis 7:64-74 (2000).   |       |  |  |
|                      | 69  | Samuel, C.E., <i>Hokkaido J Med Sci</i> <u>69</u> (6):1339-1347, (1994).  |       |  |  |
|                      | 70  | Samuel, C.E., Clinical Microbiology Reviews <u>14</u> (4):778-809, (2001).  |       |  |  |
|                      | 71  | Satoh, Y.I., et al., <i>J Interferon Cytokine Res</i> <u>19</u> :887-894, (1999).   |       |  |  |
|                      | 72  | Schröder, H.C., et al., Int J Biochem <u>24</u> (1):55-63, (1992).  |       |  |  |
|                      | 73  | Shindo, M., et al., Hepatology <u>9</u> (5):715-719, (1989).  |       |  |  |
|                      | 74  | Short, Jr., E.C., et al., Biology of Reproduction 44:261-268, (1991).   |       |  |  |
|                      | 75  | Singh, B.N., <i>Clin Pharmacokinet</i> <u>37</u> (3):213-255, (1999).   |       |  |  |
|                      | 76  | Sood, A. and Panchagnula, R., <i>Chem Rev</i> <u>101</u> :3275-3303, (2001).  |       |  |  |
|                      | 77  | Soos, J.M., et al., Journal of Neuroimmunology 75:43-50, (1997).  |       |  |  |
|                      | 78  | Stoll, B.R., et al., Journal of Controlled Release 64:217-228, (2000).  |       |  |  |
|                      | 79  | Takayama, S., et al., <i>J Interferon Cytokine Res</i> <u>19</u> :895-900, (1999).  |       |  |  |
|                      | 80  | Thorbecke, G.J., et al., Arthritis & Rheumatism <u>42(1):110-118, (1999)</u> .  |       |  |  |

| EXAMINER   |  | DATE CONSIDERED   |
|------------|--|---|
|            |  |   |
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| 4                    | 81 ·        | Trepo, C., Journal of Viral Hepatitis 7:250-257 (2000).   |           |
|                      | 82          | Tyring, S.K., Interferon: Principles and Medical Applications, Baron, et al. (eds.), Galveston TX, 1992.  |           |
|                      | 83          | Vallet, J.L., et al., "Biology of Reproduction 37:1307-1316 (1987).   |           |
|                      | 84          | Whaley, A.E., et al., Journal of Biological Chemistry <u>269</u> (14):10864-10868 (1994).   |           |
|                      | 85          | Witt, P.L., et al., <i>J Interferon Res</i> <u>12</u> :411-413, (1992).   |           |
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